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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/703,809	10/30/2000	Jeff L. DeJong	119941-1083	3391

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EXAMINER

HUTSON, RICHARD G

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 10/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/703,809

Applicant(s)

DEJONG, JEFF L.

Examiner

Richard G. Hutson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 86-95 and 97-106 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 92 is/are allowed.
- 6) ☒ Claim(s) 86-88, 90, 91, 93-99, 101, 102, and 104-107 is/are rejected.
- 7) ☒ Claim(s) 89, 100, 103 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Applicants amendment of claims 86, 97, 103 and 104 and cancellation of claims 96 and 107 in the paper of 6/10/2004, is acknowledged. Claims 86-95 and 97-106 are still at issue and are present for examination.

Applicants' arguments filed on 6/10/2004 have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claim Objections

Claims 86, 89, 97, 100, 103 are objected to because of the following informalities:

Newly amended claims 86, 97 and 103 recite " **and** wherein said protein comprises..." It is suggested that this be amended to "wherein said protein comprises..."

Claims 89 and 100 depend on rejected claims 86 and 97, respectively.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 86-88, 90, 91, 93-99, 101, 102, and 104-107 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejection is stated in the previous office action as it applied to claims 86-88, 90, 91, 93-99, 101, 102, and 104-107. In response to this rejection applicants have amended claims 86, 97, 103 and 104, cancelled claims 96 and 107 and traverse the rejection as it applies to the newly amended claims.

Applicants traverse on the basis that there is sufficient written description and information available in the art regarding structure/function relationships for claiming protein variants as disclosed and claimed by the present applicant, specifically with respect to transcription factors, e. g. the well known domains of transcription factors that have been compared by others and in the present application provide the basis for numerous structure/function studies. Applicants submit that many of these transcription factors have been crystallized and domains compared and that the current specification states clearly that these types of changes are conducted routinely in the art and the specification provides specific guidance as to what changes should be made.

Applicants argument is acknowledged in full, however, found non-persuasive. It is noted that as a preliminary comment, it is unclear as to what "types of changes" applicants are referring to in their traversal above, although, presumably applicants are

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referring to “the type of changes” that are encompassed within the genus of claimed variants that corresponds with “any type of change” as long as the protein has greater than 90% amino acid sequence identity to SEQ ID NO: 2 and comprises a transcription factor.

Applicants amendment of the rejected claims such that they are now drawn to proteins which comprises a transcription factor is not sufficient to overcome the rejection because applicants claimed function, that of “a transcription factor” is a large variable genus of proteins with the potentiality of comprising many functionally different types of transcription factors. Applicants have pointed out that many of these transcription factors have been crystallized and domains compared, and while this may be correct, “transcription factors” as class a class of proteins is a broad, variable class that as a group merely share the common characteristic that they control by some means the transcription of a gene or genes. **Insert reference or definition here!** As such by merely limiting the class of proteins to any protein having the defined structural relationship to SEQ ID NO: 2, wherein said protein is a “transcription factor” does not adequately limit the genus of claimed proteins. Specifically, the limitation that the claimed proteins must comprise “a transcription factor” is not sufficient for establishing a structure to function relationship for the claimed genus, because the claimed function of a “transcription factor” comprises many different types of proteins, that control transcription by many different unrelated complex mechanisms. For instance, applicants submitted common structural attributes that define the genus, such as conserved regions I and IV, acidic region II, praline serine and threonine rich regions

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and clathrin-like domains are not common structural attributes of all transcription factors, but merely common to the class of transcription factors that applicants invention falls into. Thus applicants traversal is found nonpersuasive.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 86-88, 90, 91, 93-99, 101, 102, and 104-106 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated protein having the amino acid sequence of SEQ ID NO: 2 or 4, does not reasonably provide enablement for any protein comprising an amino acid sequence having greater than 90% amino acid sequence identity to SEQ ID NOs: 2 or 4, wherein said protein comprises a transcription factor. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The rejection is stated in the previous office action as it applied to claims 86-88, 90, 91, 93-99, 101, 102, and 104-107. In response to this rejection applicants have amended claims 86, 97, 103 and 104, cancelled claims 96 and 107 and traverse the rejection as it applies to the newly amended claims.

Applicants traverse on the basis that applicants amendment to include a "transcription factor" is enabled throughout the specification and in in vitro translation

assays. In their traversal applicants also include the above discussion under the 112 first paragraph written description rejection.

As discussed above, applicants amendment of the rejected claims such that they are now drawn to proteins which comprises a transcription factor is not sufficient to overcome the rejection because applicants claimed function, that of "a transcription factor" is a large variable genus of proteins with the potentiality of comprising many functionally different types of transcription factors and applicants have not enabled the genus of proteins that is encompassed by those proteins having 90% identity to SEQ ID NO: 2 and comprises any transcription factor or alternatively any protein which in some way has transcriptional regulatory activity. As stated above, "transcription factors" as class of proteins is a broad, variable class that as a group merely share the common characteristic that they control by some means the transcription of a gene or genes (i.e. See Fry and Farnham, J. Biol. Chem. Vol 274, (42), pp 29583-29586, October 1999). As such by merely limiting the class of proteins to any protein having the defined structural relationship to SEQ ID NO: 2, wherein said protein is a "transcription factor" does not adequately limit the genus of claimed proteins, such that applicants have enabled the claimed genus.

Applicants argument is not found persuasive for the reasons stated above. As above, applicant is reminded that the newly added limitation that the claimed proteins comprise a transcription factor encompasses many complex and diverse activities. Thus as the specification only provides the representative species of proteins having the amino acid sequence of SEQ ID NO: 2 and 4, there is no disclosure of any particular

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structure to function/activity relationship in the claimed genus and the scope of those proteins remains large with regard to the extremely large number of proteins or transcription factors broadly encompassed by the claims. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to the teachings of those proteins having the amino acid sequence of SEQ ID NO: 2 and 4.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and **use** the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any protein having 90% identity to the amino acid sequence of SEQ ID NO: 2 or 4, wherein said protein comprises transcriptional activity. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of those proteins having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Hutson whose telephone number is (571) 272-0930. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Richard G. Hutson', with a large, sweeping flourish at the end.

Richard G Hutson, Ph.D.
Primary Examiner
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rg
9/23/2004